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predetermined setpoint after the liquid level drops below the predetermined setpoint.

af 18. (amended) The method according to claim 14, further comprising the step of:
degassing at least one of the water and the mixture of the water and the dialysis fluid
before at least one of the water and the mixture of the water and the dialysis fluid enter the at
least one proportioning unit.

19. (amended) The method according to claim 14, further comprising the step of:
heating the at least one of the water and the mixture of the water and the dialysis fluid
before at least one of the water and the mixture of the water and the dialysis fluid enter the at
least one proportioning unit.

REMARKS

I. INTRODUCTION

Claims 1 to 20 are pending in the above-captioned application. By the present amendment, claims 1-5, 8-10, 13-15 and 18-19 have been amended to better clarify the scope of the present invention. No new matter has been added herein by the present amendment, as support thereof can be found in the specification at, *inter alia*, page 6, lines 14-16; page 9, lines 10-23; and Figure 1. Applicants respectfully submit that the claims are now in condition for allowance.

II. REJECTIONS UNDER 35 U.S.C. § 112

The Examiner has rejected claims 1-13 and 15-17 under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which Applicants regard as the invention. For at least the following reasons, Applicants respectfully request that these rejections be withdrawn.

First of all, the Examiner has rejected claim 1 alleging that it was unclear what "inlet line" was being referred to therein. Applicants have herein amended claims 1-3, 5, 8-10 and 13 to clearly differentiate between the "dialysis fluid inlet line" and the "proportioning unit inlet line" in the claimed dialysis machine.

The Examiner has also rejected claim 3 alleging that it was unclear as to what was the "cutoff element" recited therein. Applicants have herein amended claims 3 and 4 to clearly recite the four separate cutoff elements recited therein.

In addition, the Examiner has also rejected claim 4 alleging that it was unclear what Applicants meant by the term "switched" recited therein. Applicants have herein amended claim 4 to cancel the claim limitation of "so that the proportioning unit is switched."

Finally, the Examiner has rejected claim 15 alleging that there was insufficient antecedent basis for the claim limitation of "the setpoint." Applicants have herein amended claim 15 to provide such antecedent basis by including the claim limitation of "a predetermined setpoint."

Thus, Applicants respectfully submit that the rejections under 35 U.S.C. § 112 have been overcome and should therefore be withdrawn.



III. REJECTIONS UNDER 35 U.S.C. § 103

The Examiner has also rejected claims 1-5 and 7-20 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,042,784 ("Wamsiedler et al.") in view of U.S. Patent No. 4,136,708 ("Cosentino et al."). Applicants respectfully submit that Wamsiedler et al. and Cosentino et al., alone or in combination, do not render obvious claims 1-5 and 7-20.

To render a claim obvious, the prior art must teach or suggest all of the claim limitations. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Moreover, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the modification must be found in the prior art and not in the Applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Wamsiedler et al. is directed to a method and apparatus for ultrafiltration in hemodialysis. Wamsiedler et al. discloses "[a] method and device for accurately determining the volume of and replacing ultrafiltrate in hemodiafiltration using an ultrafiltrate balance chamber that is subdivided by a movable partition into two balance chamber halves."

Wamsiedler et al., abstract. The device disclosed in Wamsiedler et al. includes a dialysis fluid source 9 which has a degassing pump 9a and which provides fresh dialysis fluid to a dialysis fluid chamber 4. *See* Wamsiedler et al., col. 4, lines 44-54. The device also includes a dialysis fluid balancing unit 13 having two balance chambers 14 and 15, each subdivided by a movable partition, such as a flexible membrane. *See* Wamsiedler et al., col. 4, lines 55-61.



Cosentino et al. is directed to a hemodialysate blending system. Cosentino et al. discloses “[a] system for preparation of variable hemodialysate in which a controllable pump meters multiple fluid sources of dialysate concentrates and water in controlled proportion.” Cosentino et al., abstract. Cosentino et al. further discloses a system including sources of multiple dialysate concentrates and a water source, and multiple metering and pumping assemblies for accurately controlling and adjusting proportions of the respective solutions for blending together in a holding chamber. *See* Cosentino et al., col. 2, line 64 to col. 3, line10. While in the holding chamber, the solutions are continually mixed and are delivered therefrom to a point of usage as needed by a conduit. *See* Cosentino et al., col. 3, lines 11-14.

In contrast to the teachings of Wamsiedler et al. and Cosentino et al., the dialysis machine of the present invention, as currently recited in independent claim 1 in amended form, includes the claim limitation of “wherein the equalizing chamber provides a variable buffer volume between the proportioning unit and the balancing system such that the flow rate of a dialysis fluid through the dialysis fluid chamber has no effect on the flow rate of the fresh dialysis fluid in the proportioning unit outlet line.” Likewise, the method of the present invention, as currently recited in independent claim 14 in amended form, includes the claim limitation of “wherein the equalizing chamber provides a variable buffer volume between the at least one proportioning unit and the balancing system such that the flow rate of the dialysis fluid through the dialysis fluid chamber has no effect on the flow rate of the fresh dialysis fluid into the equalizing chamber.” As described in the specification, this novel



aspect of the dialysis machine and method of the present invention provides “the advantage that the conductivity can be measured with a high accuracy regardless of changes in flow, and the metered addition of the concentrates can be performed accurately.” Specification, page 9, lines 13-15.

Neither Wamsiedler et al. nor Cosentino et al., alone or in combination, teach or suggest Applicants’ particularly claimed dialysis machine or method of operating a dialysis machine. First of all, although the Examiner alleges that the dialysis fluid source 9 disclosed in Wamsiedler et al. “may act as the equalizing chamber claimed by applicant,” Applicants respectfully disagree. The dialysis fluid source 9 disclosed in Wamsiedler et al. supplies fresh dialysis fluid to the apparatus disclosed therein; it does not provide a variable buffer volume between a proportioning unit and a balancing system such that the flow rate of a dialysis fluid through a dialysis fluid chamber has no effect on the flow rate of fresh dialysis fluid from the proportioning unit. *See* Wamsiedler et al., col. 4, lines 44-49; col. 6, lines 4-14. Likewise, although the Examiner alleges that the holding chamber 70 disclosed in Cosentino et al. “may act as an equalizing chamber,” Applicants respectfully disagree. The holding chamber 70 disclosed in Cosentino et al. allegedly ensures complete mixing of the concentrate solutions in water as an output is taken, but it does not provide a variable buffer volume between a proportioning unit and a balancing system such that the flow rate of a dialysis fluid through a dialysis fluid chamber has no effect on the flow rate of fresh dialysis fluid from the proportioning unit. *See* Cosentino et al., col. 19, lines 40-45.

Therefore, because each and every element of the claimed invention is not taught nor suggested by Wamsiedler et al. or Cosentino et al., and because there is no teaching, suggestion nor motivation in either Wamsiedler et al. nor Cosentino et al. which would motivate one of ordinary skill in the art to combine and modify these references in an attempt to arrive at the presently claimed invention, Applicants respectfully submit that the rejections of claims 1-5 and 7-20 under 35 U.S.C. § 103(a) have been overcome and should therefore be withdrawn.

The Examiner has also rejected claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Wamsiedler et al. in view of Cosentino et al., in view of U.S. Patent No. 4,770,769 ("Schael"). Applicants respectfully submit that Wamsiedler et al., Cosentino et al. and Schael, alone or in combination, do not render claim 6 obvious.

As explained above, Wamsiedler et al. in view of Cosentino et al. fail to teach or suggest the dialysis machine of the present invention, as currently recited in independent claim 1 in amended form, which includes the claim limitation of "wherein the equalizing chamber provides a variable buffer volume between the proportioning unit and the balancing system such that the flow rate of a dialysis fluid through the dialysis fluid chamber has no effect on the flow rate of the fresh dialysis fluid in the proportioning unit outlet line."

Schael does not cure the shortcomings of Wamsiedler et al. and Cosentino et al. Schael is directed to a hemodialysis apparatus with degassing means for the dialysis



• solution. According to the Examiner, "Schael discloses a dosing, mixing, and balancing dialysis apparatus with a balancing system and a dialysis solution mixing and holding chamber 100," wherein the "holding chamber 100 comprises a heating and degassing device, as well as a pressure reduction valve 52 therein." However, the holding chamber 100 disclosed in Schael does not provide a variable buffer volume between a proportioning unit and a balancing system such that the flow rate of a dialysis fluid through a dialysis fluid chamber has no effect on the flow rate of fresh dialysis fluid from the proportioning unit. Therefore, because each and every element of the claimed invention is not taught nor suggested by Wamsiedler et al., Cosentino et al. or Schael, Applicants respectfully submit that the rejection of claim 6 under 35 U.S.C. § 103(a) has been overcome and should therefore be withdrawn.

IV. CONCLUSION

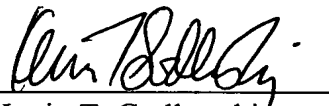
Applicants respectfully submit that the present remarks and amendments place the application in condition for allowance, and such action is respectfully requested. If for any reason the Examiner believes that contact with Applicants' attorney would advance prosecution, the Examiner is invited to contact the undersigned at the telephone number given below. The Office is authorized to charge any fees associated with this Amendment, including those under 37 C.F.R. §§ 1.16 or 1.17, to Deposit Account No. 11-0600.



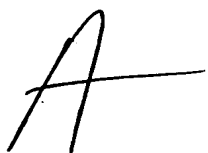
Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 1-5, 8-10, 13-15 and 18-19 have been amended as follows:

1. (amended) A dialysis machine comprising:

a dialyzer subdivided by a semipermeable membrane into a chamber for a liquid to be purified and a dialysis fluid chamber;

a dialysis fluid inlet line leading to an inlet of the dialysis fluid chamber;

a dialysis fluid outlet line leading away from an outlet of the dialysis fluid chamber;

a balancing system connected to the dialysis fluid inlet and outlet lines for balancing fresh and spent dialysis fluid; and

a proportioning device for supplying fresh dialysis fluid, the proportioning device comprising:

a water source;

at least one proportioning unit having a first chamber half and second chamber half configured to operate so that liquid is displaced from one chamber half when the other chamber half is filled with liquid;

~~an~~ a proportioning unit inlet line leading from the water source, the proportioning unit inlet line connected to an inlet of the first chamber half and an inlet of the second chamber half, and ~~an~~ a proportioning unit outlet line connected to an outlet of the first chamber half and an outlet of the second chamber half, so that the chamber halves can be alternately filled and emptied;

at least one mixing point provided in at least one of the proportioning unit inlet line and the proportioning unit outlet line;

at least one dialysis fluid concentrate source for supplying a fluid concentrate to the at least one mixing point for forming a fresh dialysis fluid; and

an equalizing chamber for the fresh dialysis fluid, the equalizing chamber connected to the proportioning unit outlet line, wherein the equalizing chamber provides a variable buffer volume between the proportioning unit and the balancing system such that the flow rate of a dialysis fluid through the dialysis fluid chamber has no effect on the flow rate of the fresh dialysis fluid in the proportioning unit outlet line.

2. (amended) The dialysis machine according to claim 1, wherein one mixing point is provided in the proportioning unit inlet line, and at least one mixing point is provided in the proportioning unit outlet line.

3. (amended) The dialysis machine according to claim 1, wherein the proportioning unit inlet line has a first inlet branch in fluid communication with the inlet of the first chamber half and a second inlet branch in fluid communication with the inlet of the second chamber half, and wherein the proportioning unit outlet line has a first outlet branch in fluid communication with the outlet of the first chamber half and a second outlet branch in fluid communication with the outlet of the second chamber half, the machine further comprising a first inlet cutoff element provided in each of the first inlet branch, a second inlet cutoff element provided in the second inlet branch, a first outlet cutoff element provided in the first outlet branch, and a second outlet cutoff element provided in the second outlet branch.

4. (amended) The dialysis machine according to claim 3, wherein the equalizing

chamber further comprises:

a liquid level indicator; and

a control unit to control the first inlet cutoff elements element, the second inlet cutoff element, the first outlet cutoff element, and the second outlet cutoff element after a liquid level drops below a predetermined setpoint ~~so that the proportioning unit is switched.~~

5. (amended) The dialysis machine according to claim 1, wherein the equalizing chamber further comprises:

an outlet connected to a supply line;

a first inlet connected to the proportioning unit outlet line; and

a second inlet connected to a recirculation line branching off from the supply line.

8. (amended) The dialysis machine according to claim 1, wherein the at least one dialysis fluid concentrate source comprises a first concentrate container for holding a first concentrate, the first concentrate container in fluid connection with a first concentrate line in fluid communication with a first mixing point in the proportioning unit inlet outlet line upstream from the proportioning unit.

9. (amended) The dialysis machine according to claim 8, wherein the at least one dialysis fluid concentrate source further comprises a second container for holding a second concentrate, the second concentrate container in fluid connection with a second concentrate line in fluid communication with a second mixing point in the proportioning unit outlet line downstream from the proportioning unit.

10. (amended) The dialysis machine according to claim 9, wherein the at least one dialysis fluid concentrate source further comprises a third container for holding a third concentrate, the third concentrate container in fluid connection with a third concentrate line in fluid communication with a third mixing point in the proportioning unit outlet line downstream from the second mixing point.

13. (amended) The dialysis machine according to claim 1, further comprising:
at least one of a degassing and a heating unit connected to the proportioning unit inlet line.

14. (amended) A method of operating a dialysis machine, comprising the steps of:
sending fresh dialysis fluid to a dialysis fluid chamber of a dialyzer, the chamber divided by a semipermeable membrane into the dialysis fluid chamber and a chamber for the liquid to be purified;

removing dialysis fluid from the dialysis fluid chamber; and
balancing spent and fresh dialysis fluid in a balancing system whereby the fresh dialysis fluid is prepared by:

filling alternately a first and a second chamber half of at least one proportioning unit with at least one of water and a mixture of water and at least one dialysis fluid concentrate;

discarding a liquid from the other chamber half;

adding at least one dialysis fluid concentrate to the liquid discarded from the other chamber half and a liquid supplied to the chamber to prepare the fresh dialysis fluid;



collecting the fresh dialysis fluid in an equalizing chamber before the fresh dialysis fluid is sent to the dialysis fluid chamber, wherein the equalizing chamber provides a variable buffer volume between the at least one proportioning unit and the balancing system such that the flow rate of the dialysis fluid through the dialysis fluid chamber has no effect on the flow rate of the fresh dialysis fluid into the equalizing chamber.

15. (amended) The method according to claim 14, wherein a liquid level is monitored within the equalizing chamber, and further comprising the step steps of:

switching the at least one proportioning unit until the liquid level is again above ~~the~~ a predetermined setpoint after the liquid level drops below a the predetermined setpoint.

18. (amended) The method according to claim 14, further comprising the step steps of:

degassing at least one of the water and the mixture of the water and the dialysis fluid before at least one of the water and the mixture of the water and the dialysis fluid enter the at least one proportioning unit.

19. (amended) The method according to claim 14, further comprising the step of:

heating the at least one of the water and the mixture of the water and the dialysis fluid before at least one of the water and the mixture of the water and the dialysis fluid enter the at least one proportioning unit.

